

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

INVERNESS MEDICAL INNOVATIONS, INC.,
INVERNESS MEDICAL SWITZERLAND GMBH, and
SPD SWISS PRECISION DIAGNOSTICS GMBH,

Plaintiffs-Counterclaim Defendants,

v.

CHURCH & DWIGHT CO., INC.,

Defendant-Counterclaim Plaintiff.

Case No. 1:10-cv-10027-DPW

JURY TRIAL DEMANDED

C&D’S PRELIMINARY INVALIDITY AND NON-INFRINGEMENT DISCLOSURES

Pursuant to Local Rule 16.6, Appendix A(2), Defendant-Counterclaim Plaintiff Church & Dwight Co., Inc. (“Church & Dwight”), by and through its undersigned counsel, hereby sets forth its Preliminary Invalidity and Non-Infringement Disclosures concerning the following asserted patents: U.S. Pat. No. 7,317,532 (“the ‘532 Patent”); U.S. Pat. No. 7,315,378 (“the ‘378 Patent”); and U.S. Pat. No. 7,239,394 (“the ‘394 Patent”) (collectively, the “Patents-in-Suit”).

Defendant submits these contentions without waiving any arguments about the sufficiency or substance of Plaintiffs’ Infringement Contentions, and without waiving any challenges to Plaintiffs’ claim constructions. Based in whole or in part on the claim interpretations that Plaintiffs appear to be asserting, and the alleged application of those interpretations to the accused product, each cited prior art reference listed below anticipates and/or renders obvious the asserted claims of the Patents-in-Suit, as described below and in the associated claim charts, attached hereto as Appendix A.

Defendant's contentions should not be construed as any admission regarding the proper construction of any asserted claim, and should not be deemed to represent or limit the claim construction that Defendant will advance in this matter. Defendant's contentions reflect Defendant's current knowledge and thinking as of this date. Defendant reserves the right, to the extent permitted by the Court and the applicable statutes and rules, to modify and supplement their contentions for good cause or for other appropriate reason, including but not limited to, after the Court issues its claim construction ruling pursuant to the Court's local patent rules and/or if Plaintiffs are allowed to modify, amend or supplement their Infringement Contentions.

A. Identification of Prior Art

Each asserted claim of the Patents-in-Suit is anticipated and/or rendered obvious by one or more of the prior art references listed below and as reflected by the charts in Appendix A:

| | Prior Art Reference | Anticipates one or more asserted claims of the patents-in-suit | Relevant to the obviousness inquiry of one or more claims of the patents-in-suit |
|----|-----------------------------|---|---|
| 1 | 5,580,794 (Allen) | | ✓ |
| 2 | 5,889,585 (Markart) | ✓ | ✓ |
| 3 | 7,214,542 (Hutchinson) | ✓ | ✓ |
| 4 | 6,194,222 (Buechler et al.) | ✓ | ✓ |
| 5 | 6,830,731 (Buechler et al.) | ✓ | ✓ |
| 6 | 4,963,498 (Hillman et al.) | | ✓ |
| 7 | 5,522,255 (Neel et al.) | ✓ | ✓ |
| 8 | 5,686,659 (Neel et al.) | ✓ | ✓ |
| 9 | 5,872,713 (Douglas et al.) | | ✓ |
| 10 | 6,315,955 (Klein) | | ✓ |

| | | | |
|----|----------------------------|---|---|
| 11 | 5,795,543 (Poto) | ✓ | ✓ |
| 12 | 5,047,351 (Makiuchi) | ✓ | ✓ |
| 13 | 5,179,288 (Miffitt et al.) | ✓ | ✓ |
| 14 | 5,316,727 (Suzuki et al.) | ✓ | ✓ |
| 15 | 5,679,584 (Mileaf et al.) | ✓ | |
| 16 | EP 0 291 194 (May) | | ✓ |
| 17 | EP 0 653 625 (Catt) | | ✓ |
| 18 | 4,849,340 (Oberhardt) | | ✓ |
| 19 | 6,187,598 (May et al.) | | ✓ |
| 20 | 7,220,597 (Zin et al.) | | ✓ |
| 21 | 6,222,619 (Herron) | | ✓ |
| 22 | 6,055,060 (Bolduan et al.) | | ✓ |

B. Preliminary Invalidity Claim Charts

Invalidity charts identifying where in each item of prior art each element of each asserted claim is found are attached hereto as Appendix A. The citations included in each chart are to be considered illustrative, not exhaustive. The references, however, contain additional support upon which Defendant might rely. Defendant also relies upon each commercial device covered by the referenced patent which may be prior art, as is the case, upon information and belief, for example for the A1C Now product for diabetes covered by the Allen '794 Patent. Additionally, each feature called out in a secondary reference and applied in the accompanying charts is intended to be exemplary of its application and may be combined in similar manner with any of the other cited primary references. For example, U.S. 6,222,619 to Herron was cited and applied as a secondary reference for the feature of determining and declaring an early positive result in an

assay. In the attached charts Herron is combined with U.S. 5,047,351 to Makiuchi, but may alternatively be combined with any other primary reference teaching the early determination of an early negative result in an assay.

Likewise, and as another example, U.S. 4,963,498 to Hillman and U.S. 6,315,955 to Klein are cited and applied as secondary references that show that determining a flow rate of a liquid sample along a liquid transport carrier was notoriously well known in the art when one is provided with (1) the time that the liquid took to flow from one detection site to another detection site and (2) the distance between the detection sites.

The reason, suggestion, or motivation to modify or combine the references in the manner claimed can be found in the explicit and/or implicit teachings of the references and the prior art as a whole, the general knowledge of those skilled in the art, including knowledge of trends in the field, and knowledge that the art is of special interest or importance in the field, and from the fact that all of the references concern methods to facilitate analyte testing, and one of ordinary skill in the art would be motivated by such obvious considerations as speed and efficiency, and other concerns common to analytical testing of particular analytes, to combine the various teachings to arrive at the claimed invention. Stated differently, the references demonstrate that there was, at the time of the alleged invention, a finite number of identified, predictable solutions for efficiently testing analytes that persons of ordinary skill in the art would have known how to successfully combine, making the claimed invention obvious.

Much of the art identified above and in the attached Appendices reflects common knowledge and the state of the art prior to the filing date of the Patents-in-Suit and/or at the time each alleged invention was made, including specifically with respect to analytical assay techniques. In many instances where a particular contention calls for, or requires, combining

references, any one of a number of references can be combined. The inclusion of certain exemplary combinations herein do not exclude other combinations based on the claim charts attached hereto, as there are many possible combinations of the references listed herein, and it is not practical, particularly at this early stage prior to further factual investigation and claim construction proceedings, to identify and list all potentially relevant combinations.

C. Invalidity for Non-Compliance with 35 U.S.C. § 112

Charts identifying Defendant's invalidity contentions pursuant to 35 U.S.C. § 112 are attached hereto as Appendix B.

D. Document Production

By separate letter, Defendant will concurrently produce any documents that are relevant to its invalidity defenses. Additional prior art can be found in the file histories for the Patents-in-Suit.

E. Preliminary Non-Infringement Claim Charts

Charts identifying Defendant's non-infringement contentions for each asserted claim of the Patents-in-Suit are attached as Appendix C.

Dated: November 23, 2010

Respectfully submitted,

/s/ James H. Shalek

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Certificate of Service

The undersigned hereby certifies that this document was filed through the ECF system on November 23, 2010 and will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and that paper copies will be sent to those indicated as non registered participants.

/s/ James H. Shalek

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